PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : **A61L 27/00, A61F 2/02**	**A1**	**(11) International Publication Number:** **WO 93/13815** **(43) International Publication Date:** 22 July 1993 (22.07.93)

(21) International Application Number: PCT/SE92/00784

(22) International Filing Date: 13 November 1992 (13.11.92)

(30) Priority data:
9200072-8 13 January 1992 (13.01.92) SE

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(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CS, DE, DE (Utility model), DK, DK (Utility model), ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).

Published
With international search report.
With amended claims.

(54) Title: AN IMPLANT

(57) Abstract

The present invention relates to an implant made of a porous non-toxic material having a total open porosity exceeding 5 % by volume but not exceeding 80 % by volume within at least one portion of the implant, which is characterized in that: communicating micropores, having a size of less than or equal to 10 µm, make up not more than 10 % of the total pore volume in said at least one portion of the implant; and at least 5 % of at least one section of the surface on the implant is covered by substantially evenly distributed pores having a pore size exceeding 50 µm.

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AN IMPLANT

TECHNICAL FIELD

The present invention relates to the field of medical technology and more specifically to the field of implantology, and relates to implants made of a porous, non-toxic material having a total open porosity exceeding 5 % by volume but not exceeding 80 % by volume within at least a portion of the implant.

BACKGROUND ART

When implant materials are used and are subjected to a substantial mechanical load, a high strength is the primary requirement. This is achieved by using essentially conventional construction materials - e.g. stainless steel, cobalt-chromium alloys, titanium and titanium-alloys, various ceramic materials and polymers. In order to fix implants, it is common practice to utilize a topographical surface or pores. In this connection special requirements as to holding and bone ingrowth must be met. A prior Swedish patent application No. 9101677-4 includes some important new aspects regarding primarily the pore size distribution. Thus, specific and complex pore size distributions can be utilized to accomodate bone ingrowth-promoting agents and to provide a satisfactory bone ingrowth in large pores.

BRIEF DISCLOSURE OF THE INVENTION

The object of the present invention is to provide an improved implant as compared to the implant according to said Swedish patent application No. 9101677-4. The present invention relates more specifically to substantially limiting the porosity of micropores by adding bone ingrowth-promoting agents through carriers, which completely or partially fill micropores as well as pores or cavities in the surface layer, which makes the need of a large available surface less important. Thus, another object of the invention is to improve the bone ingrowth and the healing not only by creating geometrical opportunities for a satisfactory ingrowth

but also by allowing a time control of the bone ingrowth, through different concentrations and release of active agents.

Generally, the purpose of the invention is to provide implants having the following characteristics: high strength, excellent biocompatibility by using bone ingrowth-promoting agents deposited in pores or in surface areas for time controlled bone ingrowth in order to achieve an improved reproduceable holding of the implant.

These and other objects of the invention can be achieved therein that communicating micropores, having a size of 10 µm or less, make up not more than 10 % of the total pore volume in said at least one portion of the implant, and that at least 5 % of at least one section of the surface of the implant is covered by substantially evenly distributed pores having a pore size not exceeding 50 µm.

The term pore size is defined, as far as pores having pore sizes smaller than or equal to 50 µm are concerned, as sizes calculated by means of conventional Hg-porosimetry, the relation between the pressure and the pore diameter (2r) being obtained through the expression:

$$p = \frac{2\ s\ \cos F}{r}$$, in which:

p = the pressure
s = the surface tension of Hg for a certain temperature; and
F = the miniscus angle (marginal angle; referens see L C Ritter and R L Drake, Ind. Eng. Chem. 17 782 (1945))

Pore sizes exceeding 50 µm are defined as sizes obtained through an optical measurement in a light microscope on a cross section of the specimens in a section made at a depth

of 0.1 µm and in a section perpendicular to the surface of the specimen, respectively.

The larger pores preferably are limited to, i.e. exist essentially only in the surface layer, more particularly are limited to a surface layer having a thickness of 3 mm, preferably 2 mm and suitably 0.3 mm. If for the rest the porosity is limited to a microporosity, i.e. to pores not larger than 10 µm in diameter and having a total volume of micropores of not more than 10 %, a high strength can be maintained.

In the pores one or several of those agents, which include bone-promoting agents, agents for bone growth or bone ingrowth, are deposited before the implantation, which agents can be included in a carrier, which can be made of a polymer, a hydrogel or the like. Due to the fact that the pores can be completely filled with the carrier and the included active agents, which both of them will successively be released, pores will gradually be available for bone ingrowth. In this way various profiles for the bone ingrowth can be achieved by means of suitable concentration levels and distributions of active agents. Also, the release rate can be controlled by selecting carriers having different degrees of solubility. Different carriers can be used in different layers and/or in different parts of the implant in order to obtain an optimal ingrowth, e.g. a fast initial ingrowth (increased short-time release) designed to provide a quick holding and subsequently a slower ingrowth designed to provide a denser and stronger bone tissue.

Additional aspects and characteristic features of the present invention are set forth in the accompanying claims.

CLAIMS

1. An implant made of a porous non-toxic material having a total open porosity exceeding 5 % by volume but not exceeding 80 % by volume within at least one portion of the implant;
c h a r a c t e r i z e d in that
- communicating micropores having a size of not larger than 10 µm make up not more than 10 % of the total pore volume in said at least one portion of the implant; and
- at least 5 % of at least one section of the surface of the implant is covered by substantially evenly distributed pores having a pore size exceeding 50 µm.

2. An implant according to claim 1, c h a r a c t e r i z e d in that the size of the micropores is less than 5 µm and preferably less than 2 µm.

3. An implant according to any of claims 1 and 2, c h a r a c t e r i z e d in that the micropores make up not more than 5 % by volume of the implant.

4. An implant according to any of claims 1-3, c h a r a c t e r i z e d in that the surface/surface layer within said at least one section of the implant is covered by pores (cavities) having a diameter size in the range 50-500 µm.

5. An implant according to any of claims 1-4, c h a r a c t e r i z e d in that the main portion of the large pores in the surface layer have a diameter size within the range 75-400 µm, preferably within the range 100-300 µm and suitably within the range 150-250 µm.

6. An implant according to any of claims 1-5, c h a r a c t e r i z e d in that the large pores (cavities)

exist in a surface layer, which has a thickness of 3 mm, preferably 2 mm and suitably 0.3 mm.

7. An implant according to any of claims 1-6, c h a r a c t e r i z e d in that said at least one portion of the implant mainly consists of one or more materials, which are selected those materials which comprise from calcium phosphate materials, titanium, cobalt-chromium-alloys, stainless steels, silicon nitride and other types of cerams, and polymers.

8. An implant according to any of claims 1-7, c h a r a c t e r i z e d in that pores or surface areas of the implant surface or parts thereof contain deposited substances having desirable medical and/or biological functions.

9. An implant according to any of claims 1-8, c h a r a c t e r i z e d in that the deposited substance is made up of one or more bone ingrowth factors, preferably one or more of the substances IGF, PDGF, BMP and TGF.

10. An implant according to any of claims 1-8, c h a r a c t e r i z e d in that the deposited substance consists up of one or more antibiotics.

11. An implant according to any of claims 1-8, c h a r a c t e r i z e d in that the deposited substance consists of Ca-compounds of phosphate-type or fluorides.

12. An implant according to any of claims 1-8, c h a r a c t e r i z e d in that hyaluronic acid is deposited in the pores.

13. An implant according to any of claims 1-12, c h a r a c t e r i z e d in that the deposited substances are

included separately or in combination, freely or in a gel and/or a polymer carrier.

14. An implant according to any of claims 1-13, c h a r a c t e r i z e d in that the deposition of substances is differentiated to various zones in order to control the growth rate and the bone tissue quality.

AMENDED CLAIMS

[received by the International Bureau on 10 June 1993 (10.06.93); original claim 1 amended; other claims unchanged (3 pages)]

1. An implant made of a porous non-toxic material having a total open porosity exceeding 5 % by volume but not exceeding 80 % by volume within at least one portion of the implant; c h a r a c t e r i z e d in

- that it has communicating micropores having a size of not larger than 10 µm, said communicating micropores making up not more than 10 % of the total pore volume in said at least one portion of the implant;
- that at least 5 % of at least one section of the surface of the implant is covered by substantially evenly distributed pores having a pore size exceeding 50 µm, and
- that the implant contains bone ingrowth-promoting agents added to the implant through carriers, which completely or partially fill the micropores as well as the pores in the surface layer of the implant.

2. An implant according to claim 1, c h a r a c t e r i z e d in that the size of the micropores is less than 5 µm and preferably less than 2 µm.

3. An implant according to any of claims 1 and 2, c h a r a c - t e r i z e d in that the micropores make up not more than 5 % by volume of the implant.

4. An implant according to any of claims 1-3, c h a r a c - t e r i z e d in that the surface/surface layer within said at least one section of the implant is covered by pores (cavities) having a diameter size in the range 50-500 µm.

5. An implant according to any of claims 1-4, c h a r a c - t e r i z e d in that the main portion of the large pores in the surface layer have a diameter size within the range 75-400 µm, preferably within the range 100-300 µm and suitably within the range 150-250 µm.

6. An implant according to any of claims 1-5, c h a r a c - t e r i z e d in that the large pores (cavities) exist in a surface layer, which has a thickness of 3 mm, preferably 2 mm and suitably 0.3 mm.

7. An implant according to any of claims 1-6, c h a r a c - t e r i z e d in that said at least one portion of the implant mainly consists of one or more materials, which are selected those materials which comprise from calcium phosphate materials, titanium, cobalt-chromium-alloys, stainless steels, silicon nitride and other types of cerams, and polymers.

8. An implant according to any of claims 1-7, c h a r a c - t e r i z e d in that pores or surface areas of the implant surface or parts thereof contain deposited substances having desirable medical and/or biological functions.

9. An implant according to any of claims 1-8, c h a r a c - t e r i z e d in that the deposited substance is made up of one or more bone ingrowth factors, preferably one or more of the substances IGF, PDGF, BMP and TGF.

10. An implant according to any of claims 1-8, c h a r a c - t e r i z e d in that the deposited substance consists up of one or more antibiotics.

11. An implant according to any of claims 1-8, c h a r a c - t e r i z e d in that the deposited substance consists of Ca-compounds of phosphate-type or fluorides.

12. An implant according to any of claims 1-8, c h a r a c - t e r i z e d in that hyaluronic acid is deposited in the pores.

13. An implant according to any of claims 1-12, c h a r a c - t e r i z e d in that the deposited substances are included separately or in combination, freely or in a gel and/or a polymer carrier.

14. An implant according to any of claims 1-13, c h a r a c - t e r i z e d in that the deposition of substances is differentiated to various zones in order to control the growth rate and the bone tissue quality.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 92/00784

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61L 27/00, A61F 2/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61L, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EDOC, WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO, A1, 9221302 (LUCOCER AKTIEBOLAG), 10 December 1992 (10.12.92) --	1-14
A	EP, A2, 0267624 (ASAHI KOGAKU KOGYO), 18 May 1988 (18.05.88), page 3, line 47 - line 58, abstract, claims --	1-14
A	US, A, 4957509 (TAMARI ET AL), 18 Sept 1990 (18.09.90), column 3, line 1 - line 9, abstract, claims --	1-14

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
19 April 1993	21 -04- 1993
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE, C2, 3717818 (ASAHI KOGAKU KOGYO K.K), 2 January 1992 (02.01.92), column 3, claims	1-14

INTERNATIONAL SEARCH REPORT

Information on patent family members

31/03/93

International application No.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 9221302	10/12/92	AU-A- 1908192	08/01/93
		SE-B- 468502	01/02/93
		SE-A- 9101677	04/12/92
EP-A2- 0267624	18/05/88	JP-B- 1049501	25/10/89
		JP-A- 63125259	28/05/88
US-A- 4957509	18/09/90	JP-A- 62202884	07/09/87
DE-C2- 3717818	02/01/92	FR-A- 2607008	27/05/88
		GB-A,B- 2192389	13/01/88
		JP-B- 2005087	31/01/90
		JP-A- 62281953	07/12/87
		US-A- 5064436	12/11/91